STUDY REPORT

Study Title

PARTICLE SIZE DISTRIBUTION (GRANULOMETRY) TEST WITH[redacted]

Author:
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Study completion date:
2011/7/28

Test Facility

[redacted]
Taiwan, R.O.C.

Report No.
P252-501-R7.14

GLP compliance
NO

SUMMARY

Information on a substance ´s particle size distribution (granulometry) is one of the standard information requirements under Annex VII, section 7.14 of Regulation (EC) No 1907/2006 (hereinafter "REACH Regulation"). The original particle size distribution is highly dependent on the industrial processing methods used and can also be affected by subsequent environmental or human transformations. There are no QSPR/QSAR tools available for predicting particle size and the data will therefore need to be experimentally determined.

This test determined particle size distribution (granulometry) of substance [redacted] in accordance with REACH and Regulation (EC) No 440/2008[2] as well as their amendments .

[redacted] is a crystalline power and has relatively large diameter. According to Methods to determine particle size distribution of the material as it is [3], the test was conducted with microscopic examination method.

Mass median diameter: 103.38 microns
Particle size (percentile):
16 % less than 50.57 microns
25 % less than 58.12 microns
75 % less than 171.08 microns

[1] List number for this substance is assigned by ECHA on 26/07/2011 (Inquiry No.: [redacted].
[2] EU Regulation on the Testing Methods for REACH.
[3] Guidance on information requirements and chemical safety assessment Chapter R.7a: Endpoint specific guidance, Table R.7.1-30, ECHA, 2008

TEST SUBSTANCE

Substance Name:	[redacted]
EC No. :	[redacted](assigned by ECHA)
IUPAC Name:	[redacted]
CAS No. :	[redacted]
CAS Name:	[redacted]
Trade name:	[redacted]
Substance type:	Mono constuitent substance
Purity:	> 99%
Molecular formula:	[redacted]
Molecular Weight:	[redacted]
Impurities:	It is not technically possible to identify them. Number of unknown impurities: 2
Aggregate state at room temperature:	Crystalline powder
Colour:	White
Odour:	Odorless
Storage conditions:	

METHOD

Study period

Initiated date: 07/28/2011
Completed date: 07/28/2011

Type of distribution

volumetric distribution

Test Guideline/Method

Method: Microscopic examination

Principles of method:

Method and details	Material and size range	MMAD
Microscopic examination It is preferable to prepare samples directly in order not to influence shape and size of the particles. This method determines distribution of particles of respirable and inhalable size and does not refer to airborne dust or dispersed or nebulised particles.	Particles of all kinds Size range: 0.5-5000 microns (light microscope) and < 0.1 – 10 microns (SEM/TEM)	MMAD cannot be determined.

MMAD = mass median aerodynamic diameter

Test material equivalent to submission substance identify
YES

Test procedure:

PLEASE HERE INDICATE. Furthermore the following information should be presented:

- Expected % change of reported values in the future (e.g. variations between production batches.)
- Sample preparation methods and analysis methods used
- Approximate information on particle shape (e.g. spherical, platelike, needle shaped)
- Lot number, sample number
- Suspending medium, temperature, pH
- Concentration
- Stoke's (effective hydrodynamic) radius Rs, distribution for 2<Rs<200 micron
- Mean value and approximate area (%) of any resolvable peak in Rs distribution
- % of particles with Rs <2 micron and Rs >200 micron

RESULT AND DISCUSSION

Mass median diameter: __103.38____

No.	Size (µm)	Distribution (%)
1	61	28
2	50	21
3	187	80
4	155	74
5	206	86
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Candice
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(Name and Signature of person responsible for the study)